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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/054,482	11/13/2001	Hiroyoshi Kishi	35.G1972 Div. I	6512

5514 7590 03/11/2003

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EXAMINER

KHARE, DEVESH 3

ART UNIT PAPER NUMBER

1623

DATE MAILED: 03/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/054,482

Applicant(s)

KISHI ET AL.

Examiner

Devesh Khare

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s) ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claims 1-11 are currently pending in this application.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under the second paragraph of 35 U.S.C. 112, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. Claims 1 and 6 rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements, such omission amounting to a gap between the elements. See MPEP § 2172.01. The omitted element is: "second component". Term "second component" is not defined, and the definition is indeed critical to the identity of the glycopolymer instantly claimed. The definition of a compositional component is the omitted element.

All claims rejected which depend from claim 1 (claims 1-6).

2. In claim 7, the lack of definition for a plurality of molecular chains (of undisclosed length and composition) and the lack of definition for the "at least one repeating unit" renders claims 7-11 indefinite.

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35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Iritani et al. (U.S. Patent 5,576,020 or 5,6444,012).

Claims 1-11 are directed toward crosslinked glycopolymer, which have a repeating unit, which is comprised of:

- (1) a saccharide consisting of glucopyranose
- (2) a bifunctional or polyfunctional aliphatic compound consisting of a dicarboxylic acid, a diol, a diamine and a diisocyanate.

Additional claim limitations include a bifunctional aliphatic compound polyvinyl alcohol (claim 4), saccharide chains are crosslinked through the saccharide (claims 5 and 9) or through the bifunctional compounds (claims 6 and 10) and the repeating unit having a vinyl group (claim 11).

Iritani et al. teach the copolymer compounds which are comprised of a repeating unit, which can be saccharide, oligosaccharide or polysaccharide (see col.3, lines 25-59) and a bifunctional agent (see col.4, line 12 through col.6, line 64 in). Iritani et al. disclose a wide range of saccharides especially the saccharides consisting of glucopyranose such

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as cellobiose and raffinose (col. 3, lines 58-59) which are appropriate for use in their invention and envision the use of both dicarboxylic acid (col.4, lines 19-21) and diamino bifunctional agents (col. 4, lines 55-57). Iritani et al. also disclose in col. 3, lines 47-50, the modes of cross linkage between glucose units, which are rendered obvious by the disclosure. Iritani et al. differ from the applicant's invention that Iritani et al. do not provide an explicit example of a glycopolymer where the saccharide chains are crosslinked through the bifunctional compounds or the presence of a vinyl group in the repeating chains, however Iritani et al. do provide motivation to use various types of saccharides and bifunctional agents to produce the copolymer compounds. Use of a known member of a class of materials in a process is not patentable if other members of the class were known to be useful for that purpose, even though results are better than expected. In the absence of chemical names or structural formulae for "a second component", "molecular chains with at least one repeating unit", and the location of cross-linking locations, the Iritani et al. patent is seen to render the instantly claimed glucopolymers *prima facie* obvious.

Therefore, one of ordinary skill in the art would have found the applicants crosslinked glycopolymer, to have been obvious at the time the invention was made having the above reference before him because Iritani et al. teach the copolymer compounds which are comprised of a repeating unit, which can be saccharide, oligosaccharide or polysaccharide and a bifunctional agent. A skilled artisan would be motivated to make routine modifications to produce a glycopolymer for pharmaceutical delivery.

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State of the Art References

The following references further reflect the current state of the art:

Couture et al. (U.S. Pub. No. 2003/0027787) -discloses a crosslinked polysaccharide.

Klohr et al. (U.S. Patent 6,489,468) –discloses esters of oligo- and polysaccharides.

Roth et al. (U.S. Patent 6,204,369) – discloses alkylpolyglycosides.

Any inquiry concerning this communication or earlier communications from the

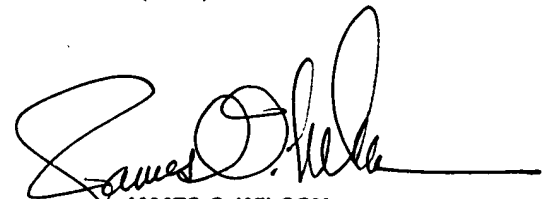
Examiner should be directed to Devesh Khare whose telephone number is (703)605-

1199. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 703-308-4624. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
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March 5,2003



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600